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T-193 P.003/014 F-193

IN THE UNITED STATES PATENT AND TRADEMARK OFFICERECEIVED
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Application of:

Docket No. 30296-A

NAGARAJA et al.

Serial No. : 09/841,786

Group Art Unit No. 1645

Filed: April 24, 2001

Examiner: P. Baskar

RECOMBINANT FUSOBACTERIUM
NECROPHORUM LEUKOTOXIN
VACCINE AND PREPARATION
THEREOFAssistant Commissioner of Patents
Washington, D.C. 20231

Sir:

DECLARATION

I, Dr. J. Glenn Songer, declare and state as follows:

1. I am a professor of Veterinary Science/Microbiology at the University of Arizona in Tucson, Arizona.

2. My *curriculum vitae* is attached hereto as Exhibit A. As shown therein, I hold a Ph.D. degree and have 25 years of experience and expertise in the areas of DNA sequencing and manipulation of gene sequences as well as the genetics of toxogenesis in bacteria.

3. I have reviewed in detail U.S. Patent Application Serial No. 09/841,786 (the '786 application) for Nagaraja et al. at the request of the Kansas State University Research Foundation, assignee of the above-identified patent application. In particular, the '786 application discloses that sequences having certain percentages of homology with specific disclosed peptide or protein sequences would be enabled such that one of ordinary skill in the art would be able to make and use the invention commensurate in scope with the claims, without undue experimentation. It was upon this basis that claims reciting a certain percentage of homology with a disclosed peptide or protein

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sequence were rejected. Therefore, I was asked to review the patent application and to use my expertise to render an opinion about whether the specification enabled one of ordinary skill in the art to make and use the invention commensurate in scope with the claims.

4. As a preliminary matter, people of ordinary skill in the art of manipulating protein and peptide sequences have a good idea of the potential outcomes of a wide variety of manipulations of the protein sequence. Such knowledge permits them to make substitutions or variations which have very little or no effect on the function of the sequence.

5. Based upon my own experience, I am of the opinion that sequences having at least 87% sequence homology with a specifically disclosed sequence in the '786 application would exhibit similar function with those sequences having a higher degree of sequence homology with the disclosed sequences, up to and including the disclosed sequences themselves. Furthermore, one of ordinary skill in the art would be able to easily construct sequences having 87% sequence homology with one of the disclosed sequences and retain the desired function of the sequence, without undue experimentation.

6. I further declare that all statements made herein of my own knowledge are true and all statements made on information and belief are believed to be true, and further that those statements were made with the knowledge that wilful, false statements and the like are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code, and such wilful false statements may jeopardize the validity of any patents issued from the patent application.

Date: 7 August 2002


DR. GLENN SONGER